

From the Director's Desk...

TSNRP has undergone many changes in the last two and a half years. If you've been involved with the program for a few years, you many have noticed these changes, one of which is reporting on the progress of your study.

In an effort to keep investigators informed, the TSNRP web site has been greatly expanded since October 2000, and now includes opportunities for dissemination; application eligibility, requirements, and all necessary forms; previously funded TSNRP research with findings; references

and relevant links; and Resource Center activities.

With heightened activity here and abroad, many of you have taken on additional job responsibilities, and may have little time to routinely check the TSNRP website for updates. Enter our new quarterly newsletter! Geared toward keeping TSNRP investigators up on program changes and happenings, as well as on accomplishments of their TSNRP colleagues, we hope the newsletter will provide networking avenues between and among the three services' active duty, re-

serve, guard, and retired military nurse researchers.

We hope you find the information in the newsletter helpful, and look forward to your comments!

Diep Duong
Lt Col, USAF, NC

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Grant Camp 2003: Proposal-Writing Workshop

TSNRP invites active duty and reserve Army, Air Force, and Navy nurses with a research plan and who have not previously participated in a TSNRP-sponsored Grant Camp to participate in Grant Camp 2003, a 2-phased workshop. Phase I covers all aspects of proposal development, from pre-submission activities to packaging the application, even alerting participants to fatal flaws to avoid in writing a proposal. Faculty from academia and the military will discuss *Principles for Success in Grants De-*

velopment, Measurement, Methods, Human Subject Protection and IRB, and the *TSNRP Review Process*. Participants have daily opportunities for one-on-one consultation with individual faculty mentors to deal with concerns specific to their own proposals. Phase II familiarizes attendees with the scientific review process through hands-on participation in mock reviews. This year, Grant Camp's 1st



phase is scheduled for 15-20 June 2003; the 2nd phase will take place on 19-20 September. Commitment to attend both phases is required. Sponsorship will be provided to cover registration, travel costs, and per diem. Application deadline is 30 March 2003.

After last year's Grant Camp, 75 percent of 14 participating military nurses

made a commitment to submit a grant proposal to TSNRP or another funding source within the next 12 months. Five participants submitted proposals for the first of the FY03 Calls for Proposals. Last year's participants were enthusiastic about the Camp ... "[The TSNRP Grant Camp was] perfect for proposal writers," commented one satisfied participant.

Visit the TSNRP website www.usuhs.mil/tsnrp or call the TSNRP office for more information.

From the Grant Specialists.....

In each newsletter, TSNRP Grant Specialists will choose a topic that frequently surfaces in discussions with Principal Investigators and/or grantee organizations. We'll also present new or revised information related to grant management. If you have a topic you'd like to see in this column, contact your TSNRP Grants Specialist, or send an email to the TSNRP office at tsnrp@usuhs.mil.

Adverse Events – What Are They and What You Need To Do About Them

Problems involving risk to participants may occur during the course of a research study and require appropriate and timely responses. "An adverse event (AE) is an occurrence or situation during the course of a research project that was 1) harmful to a subject taking part in the research, or 2) increased the probability of harm to subjects taking part in the research" (Cornell University Committee on Human Subjects, 2002).

Federal regulations governing the use of humans in research do not provide clear definitions or guidance for reporting AE's. The regulations state the institution that granted local approval to conduct the research must have "written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Department or Agency head, of any unanticipated problems involving risks to subjects or others or any serious or continuing non-compliance with this policy or the requirements or determinations of the IRB..." (45CFR46). Their definition of "prompt" and "unanticipated problems" can leave the decision-making investigator questioning what and when to report. "Clearly, any unanticipated problem involving 'risk' that ultimately results in harm to the subject and is related to a research intervention encompasses a reportable AE" (Prentice et al, 2002). Local IRBs' policies, even within one service, may vary. Therefore, "an investigator is responsible for knowing the policies of the local IRB, adhering to these policies, and maintaining a copy of the policies in the study file. An investigator is also responsible for the accurate documentation, investigation and follow-up of all possible study-related adverse

events" (NIH, 2003),

When an unanticipated event occurs, the Principal Investigator must initially decide whether the event is related to the research, can be categorized into a series of similar events resulting in a need to change the protocol and/or consent form, or is serious enough to require reporting to the local IRB. If it is, the PI must immediately report the event. If the Principal Investigator has any doubt about whether a problem involved risk, TSNRP urges erring on the side of caution and over-reporting, and seek guidance from the local IRB. When in doubt, ask!!!



Some examples of unanticipated events that require reporting, according to the University of California, Irvine's Office of Research and Graduate Studies include:

1. Death
2. Hospitalization (including extension of a planned hospital stay)
3. Unanticipated negative effect requiring treatment
4. Unusual or high frequency of expected effects (as described in the "Risks" section of the approved informed consent document)
5. Any other suspicious negative effect when, in the opinion of the Lead Researcher, there may be a relationship to the study
6. Birth defect/congenital anomaly (adverse pregnancy outcome following exposure to study procedures prior to conception or during pregnancy)

Should an adverse event occur on your TSNRP study, follow your local IRB's instructions for reporting the occurrence. Additionally, fax TSNRP a copy of the local IRB's notification within 24-48 hours of the event; the notification will be forwarded for secondary IRB review at the Uniformed Services University.

As always, if any you have any questions or concerns, contact the TSNRP office immediately.

References:

Code of Federal Regulations. Title 45A- Department of Health and Human Services; Part 46- Protection of Human Subjects. Revised 13 Nov 2001. Access date 7 Jan 2003. World Wide Web <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.103>

Cornell University Committee on Human Subjects. What is an adverse event? Updated 20 Aug 2002. Access date 7 Jan 2003. World Wide Web <http://www.osp.cornell.edu/Compliance/UCHS/Adverse.htm>

National Institutes of Health. Guidance on Reporting Adverse Events to Institutional Review Boards for NIH-Supported Multicenter Clinical Trials. 11 Jun 1999. Access date 7 Jan 2003. World Wide Web <http://grants.nih.gov/grants/guide/notice-files/not99-107.html>

University of California, Irvine. Human Subjects: Reporting Potential Adverse Experiences/Events. Updated 11 Feb 2002. Access date 7 Jan 2003. World Wide Web <http://www.rgs.uci.edu/hs/advrse.htm#adverse>

Prentice, E, Epperson, K, Kratochvil, C, & Gordon, B. (2002). IRB Review of Adverse Events. In R Amdur and E Bankert (eds) *Institutional Review Board: Management and function* (pp. 297-300). Boston: Jones and Bartlett Publishers.



Download this:

TSNRP has revised its reporting formats. Be sure to download the new Progress Report format and Final Report format from our website at www.usuhs.mil/tsnrp/managing/

The great tragedy of science - the slaying of a beautiful hypothesis by an ugly fact.

**T H Huxley
(English scientist, 1887-1975)**

In the Spotlight...

In this column we spotlight a TSNRP nurse researcher and his/her current study. This issue's spotlight is on COL (ret) Linda Yoder and her FY99 study "*Longitudinal Outcomes from a Military Burn Center.*"

COL Linda Yoder, recently retired from the Army Nurse Corps, has been actively involved in conducting nursing research and coaching junior nurse researchers. She began working as a full-time Army Nurse Researcher in 1994 and since that time has been involved in multiple, simultaneous studies as a Principal, Co-, and Associate Investigator, demonstrating not only her passion for research, but her close ties with fellow nurse researchers. Currently, COL Yoder is the Principal Investigator for the TSNRP-funded study that is evaluating the long-term outcomes of a military burn center, outcomes such as quality of life issues for burn patients and costs related to burn treatment. The results of the study may one day assist in the design of an effective



and efficient post-burn rehabilitation program.

Although COL Yoder retired from the Army Nurse Corps in 2002, she continues to lead this important study. She recently accepted a high-profile, newly created position at the National Institutes of Health as the Program Director for Nursing Research and Outcomes Management. Assisting COL Yoder on her busy study is retired Army Major Michael Yates. Yates, as Project Director, demonstrates endless dedication, commitment, and zest for nursing research. Through the endeavors of the Principal

Investigator and her Project Director, this research study has overcome many challenges and obstacles, some common and others not so common to nursing research. As an example, 11 months into data collection, all human use research was halted at their performance site. No date for resuming the study was provided leaving the team in the position of finding alternative ways to keep track of their enrolled subjects. And the intrepid Yates did just that.

After 6 months, the team was allowed to

continue subject enrollment and resume the research, but was faced with the aftermath of September 11. Many of the beds at the data collection facility were held open for potential burn victims from the Pentagon and NYC, affecting recruitment.

COL Yoder and her Project Director are a model for teamwork. Although 1,605 miles, 26 hours, and a time zone separate them, their cohesiveness and dedication to the research study is apparent in all they do. Despite the totally unpredictable challenges COL Yoder's research study has faced, it is well on its way to becoming the first-ever longitudinal outcomes database of burn victims treated in the military burn center. And at last count, they are more than halfway through subject enrollment.

COL Yoder hopes this study will fill in the "lack of research examining the outcomes of burn patients once they have survived their burn injury and then have been faced with going home, back to work, etc." Through this groundbreaking research, nursing care will be facilitated at the bedside, and the quality of life for burn victims greatly enhanced. To read more about this study, go online at: www.usuhs.mil/tsnrp/funded/fy1999/yoder.html.

SENATOR INOUE RECOGNIZED

Senator Daniel K. Inouye (D-Hawaii) was instrumental in the initial and in all subsequent Congressional appropriations for the TriService Nursing Research Program. In collaboration with the Army, Air Force, and Navy Nurse Corps, TSNRP honored Senator Inouye's support of military nursing, and military nursing research. In a videotaped ceremony held in the Senator's office, BG Barbara Brannon, BG William Bester, and RADM Nancy Lescavage presented a crystal award etched with the three Nurse Corps' insignias to Senator Inouye. Senator Inouye's overall support for nursing, and nursing research, was later recognized during the 2002 State of the Science Congress (26-28 September 2002, Washington, DC), attended by over 700 national and international nursing leaders and prominent nurse scientists. In the videotape, shown during the congress' opening ceremonies,



Lt Col Duong signs an autograph for the TSNRP office.

Senator Inouye explained the roots of his support for military nurses extend back to his hospitalization and recuperation from injuries he sustained during WWII. *"I'm sure I speak for all men and women who have had the great fortune to be served by our military nurses, whether on the sea, or on land, or in the air. It's because of them that many of us are here, healthy, and I'm certain that I express their gratitude."*

To view the videotape in its entirety, go online at www.usuhs.mil/tsnrp/about/.

Keep in touch!!!



Update your contact information through our website at www.usuhs.mil/tsnrp/updatecontact.html

Never doubt that a small group of thoughtful, committed citizens can change the world. Indeed, it's the only thing that ever has.

Margaret Mead

Check us out on the
web!
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**TRISERVICE NURSING
RESEARCH PROGRAM**

TWO AWARD CATEGORIES!!

Two new funding categories were announced by TSNRP in November 2002. These 2 new categories resulted from suggestions by the military nursing research consultants, military nurse researchers and clinicians, and Nurse Corps leadership during TSNRP's Strategic Refinement Conference (August 2002).

The first new award, "**Research Fellow Award**," aims to provide mentored experience to Masters and Doctoral prepared military nurses, for the development of specific research-related skills. The award is capped at \$75,000 in direct costs for support over a 1-year period. All **active duty** Masters and Doctoral prepared Nurse Corps Officers may apply. The application deadline for this exciting award category is **4:00 p.m. EST, 18 March 2003**. We anticipate the earliest start date for this award will be August 2003.

The second new funding category, "**Fast Track Award**," aims to facilitate rapid implementation of short-term research of emerging service-specific questions or concerns. This award is capped at \$15,000 in direct costs to support a period not to exceed 15 months. All **experienced** Nurse

Corps researchers are invited to apply; owing to the nature of this award, students and novice researchers may not apply. There will be 4 submission periods for this innovative award:

Letter of Intent Deadline	Application Deadline
4 March 2003	1 April 2003
6 May 2003	3 June 2003
September 2003	October 2003*
December 2003	January 2004*

**Deadlines for the Oct. 2003 and Jan. 2004 deadlines will be announced in the FY2004-A Call for Proposals*

More information on application requirements for these new categories can be found online at www.usuhs.mil/tsnnp. And, as always, call our office at 301.295.7077 for more information.